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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Bruce Gluckman

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EXAMINER

FAIRCHILD, MALLIKA DISPAYAN

ART UNIT

PAPER NUMBER

4115

NOTIFICATION DATE

DELIVERY MODE

01/07/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,421	GLUCKMAN ET AL.	
	Examiner	Art Unit	
	MALLIKA D. FAIRCHILD	4115	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because elements of Figures 3-7 are unclear. The text in figure 3 is very small and unreadable and figures 4-7 have filled triangles, squares and circles and it is unclear what these symbols denote. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5, 9, 13, 27, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1, 5, 9, 13 are incomplete for not having the step of detecting a response during the interictal state in order to compare if the response of the neural system to the stimulus is different from the response during the interictal state.

4. Claim 27 is incomplete for not having the step of detecting the response of the neural system during non-pre seizure times in order to compare if the response of the

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neural system to each of the said phases of the stimulus differ from each of the phases of the neural system from non-pre-seizure times.

5. Claim 28 is incomplete for not having the step of detecting a previous response of the neural system to the stimulus in order to determine whether the response of the neural system to the stimulus is different from the previous response to a stimulus.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-17, 21-23, 25-28 rejected under 35 U.S.C. 102(e) as being anticipated by Archer et al (US 6690974 B2, hereinafter "Archer et al").

8. In regards to Claim 1, Archer et al disclose a method of applying an electrical stimulus to a neural system ("brain"), detecting the response of the neural system ("brain electrical activity") to the stimulus and determining whether response is different during the interictal state whereby an impending seizure is detected (Column 2, lines 50-58). The electrical stimulus is low frequency (Column 15, line 36-51).

9. In regards to Claim 2, Archer et al disclose the electrical stimulus is subthreshold ("non-responsive", Column 7, lines 6-48).

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10. In regards to Claim 3, Archer et al disclose the electrical stimulus is continuous (“sinusoidal”, Column 15, lines 36-51).

11. In regards to claim 4, Archer et al disclose that the electrical stimulus comprises of an arbitrary waveform that is determined adaptively by the magnitude and frequency of a preceding or concurrent response (Column 5, lines 36-44).

12. In regards to Claim 5, Archer et al disclose a method of applying an electrical stimulus to a neural system (“brain”), detecting the response of the neural system to the stimulus and determining whether response is different whereby an impending seizure is detected. The electrical stimulus is subthreshold (“non-responsive”, Column 7, lines 6-48).

13. In regards to Claim 6, Archer et al disclose the electrical stimulus is low frequency (Column 15, line 36-51).

14. In regards to Claim 7, Archer et al disclose the electrical stimulus is continuous (“sinusoidal”, Column 15, lines 36-51).

15. In regards to claim 8, Archer et al disclose that the electrical stimulus comprises of an arbitrary waveform that is determined adaptively by the magnitude and frequency of a preceding or concurrent response (Column 5, lines 36-44).

16. In regards to Claim 9, Archer et al disclose a method of applying an electrical stimulus to a neural system (“brain”), detecting the response of the neural system to the stimulus and determining whether response is different whereby an impending seizure is detected. The electrical stimulus is continuous (“sinusoidal”, Column 15, lines 36-51).

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17. In regards to Claim 10, Archer et al disclose the electrical stimulus is low frequency (Column 15, line 36-51).

18. In regards to claim 11, Archer et al disclose the electrical stimulus is subthreshold ("non-responsive", Column 7, lines 6-48).

19. In regards to claim 12, Archer et al disclose the electrical stimulus comprises of an arbitrary waveform that is determined adaptively by the magnitude and frequency of a preceding or concurrent response (Column 5, lines 36-44)

20. In regards to claim 13, Archer et al disclose a method of applying an electrical stimulus to a neural system ("brain"), detecting the response of the neural system to the stimulus and determining whether response is different whereby an impending seizure is detected. The electrical stimulus comprises of an arbitrary waveform that is determined adaptively by the magnitude and frequency of a preceding or concurrent response (Column 5, lines 36-44)

21. In regards to Claim 14, Archer et al disclose the electrical stimulus is low frequency (Column 15, line 36-51).

22. In regards to claim 15, Archer et al disclose the electrical stimulus is subthreshold ("non-responsive", Column 7, lines 6-48).

23. In regards to Claim 16, Archer et al disclose the electrical stimulus is continuous ("sinusoidal", Column 15, lines 36-51).

24. In regards to claim 17, Archer et al discloses that the stimulus is characterized by current or voltage (Column 7, lines 34-35).

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25. In regards to Claim 21, Archer et al discloses that a plurality of stimuli is applied and the interval between each stimulus is capable of being more than 1 second (Column 7, lines 29-31).

26. In regards to Claim 22, Archer et al detect the response by measuring the neuronal activity (" brain electrical activity") of the neural system (Column 2, lines 50-55).

27. In regards to Claim 23, Archer et al disclose that the measuring of the neuronal activity is performed simultaneously and continuously (Column 2, lines 50-55)

28. In regards to Claim 25, Archer et al disclose that the stimulus is " non responsive" which implies that the frequency and amplitude of the stimulation is insufficient to evoke action potentials in the neurons that comprise the neural system.

29. In regards to Claim 26, Archer et al disclose a method further comprising when an impending state is detected, applying an electrical stimulation (Column 6, lines 14-21) to the neural system ("brain") wherein the magnitude and polarity of the said oriented field is changed in response to the measured neuronal activity (Column6, lines 25-32) and the measuring of the neuronal activity is performed simultaneously and continuously with the applied field (Column 16, lines 7-12).

30. In regards to claim 27, Archer et al disclose a method of applying a stimulus having a waveform comprising a positive, negative, and zero phases (See Fig. 3), to a neural system (" brain"), detecting the response of the neural system to the stimulus, and determining whether the responses to each of said phases of the stimulus differ

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from responses to each of said phases during non-pre-seizure times, whereby a pre-seizure state is detected (Column 2, lines 50-58) .

31. In regards to Claim 28, Archer et al disclose a system capable of applying a stimulus to a neural system (“ brain”), detecting the response (“ brain electrical activity”) of the neural system to the stimulus, and determining whether the response to the stimulus is different from a previous response to a stimulus (Column 2, lines 50-58).

Claim Rejections - 35 USC § 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

33. Claims 18-20, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archer et al (US 6690974 B2, hereinafter “Archer et al”) as applied to claim 1 above, and further in view of Gluckman et al (US 6665562 B2, hereinafter “Gluckman et al”).

34. In regards to claim 18, Archer et al disclose the essential features of the claimed invention except for the stimulus being characterized by field strength. Gluckman et al disclose the stimulus as being characterized by field strength wherein the stimulus is less than 1000mV/mm (Column 6, lines12-16). It would have been obvious to one having ordinary skill in the art to at the time of the invention to modify Archer’s invention by using field electrodes to provide a stimulus characterized by field strength of less

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than 1000mV/mm in order to use Archer's system to provide a stimulation which involves the application of electric fields.

35. In regards to claim 19, Archer et al disclose the essential features of the claimed invention except for the stimulus being oriented parallel to the somatic-dendritic axis. Gluckman et al disclose the stimulus is oriented parallel to the somatic-dendritic axis (Column 5, lines 43-46). It would have been obvious to one having ordinary skill in the art to at the time of the invention to modify Archer's invention by using electrodes positioned such that the stimulus is oriented parallel to the somatic-dendritic axis in order to use Archer's invention by applying an electric field oriented in a particular direction and in this case parallel to the somatic-dendritic axis.

36. In regards to claim 20, Archer et al disclose the essential features of the claimed invention except for the stimulus being an electric field produced using two field electrodes positioned external to the neurons in the neural system. Gluckman et al disclose the stimulus is an electric field produced using two field electrodes positioned external to the neurons in the neural system (Column 9, lines 25-51). It would have been obvious to one having ordinary skill in the art to at the time of the invention to modify Archer's invention by using field electrodes positioned external to the neurons of the neural system in order to provide a stimulus characterized by field strength.

37. In regards to claim 24, Archer et al disclose the essential features of the claimed invention except for the measured neuronal activity being characterized by root-mean-square. Gluckman et al disclose the measured neuronal activity is characterized by root-mean-square (Column 14, lines 5-9). It would have been obvious to one having

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ordinary skill in the art to at the time of the invention to modify Archer's invention by using root-mean-square to characterize the neuronal activity in order to detect an impending seizure.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gielen et al (US 6671555 B2) is one of many teachings of a system and method for predicting the likelihood of an impending neurological episode such as an epileptic seizure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MALLIKA D. FAIRCHILD whose telephone number is (571) 270-7043. The examiner can normally be reached on Monday through Thursday 7.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steve McAllister can be reached on (571) 272-6785. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MALLIKA D FAIRCHILD/
Examiner, Art Unit 4115

/Steven B. McAllister/
Supervisory Patent Examiner, Art Unit 3749